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I U C L I D

Data Set

Existing Chemical : ID: 3806-34-6
CAS No. : 3806-34-6
EINECS Name : O,O'-dioctadecylpentaerythritol bis(phosphite)
EC No. : 223-276-6
Molecular Formula : C41H82O6P2

Producer related part
Company : Epona Associates, LLC
Creation date : 28.11.2006

Substance related part
Company : Epona Associates, LLC
Creation date : 28.11.2006

Status :
Memo : Chemtura Weston 618

Printing date : 18.12.2006
Revision date :
Date of last update : 18.12.2006

Number of pages : 16

Chapter (profile) : Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile) : Reliability: without reliability, 1, 2, 3, 4
Flags (profile) : Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE),
Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1. General Information

Id 3806-34-6

Date 18.12.2006

1.0.1 APPLICANT AND COMPANY INFORMATION

Type : cooperating company
Name : Chemtura Corporation
Contact person :
Date :
Street :
Town :
Country :
Phone :
Telefax :
Telex :
Cedex :
Email :
Homepage :

28.11.2006

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type : typical for marketed substance
Substance type : organic
Physical status : solid
Purity : ca. 95 % w/w
Colour : White
Odour :

Remark : Powder
28.11.2006

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

1.3 IMPURITIES

1. General Information

Id 3806-34-6
Date 18.12.2006

1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.6.3 PACKAGING

1.7 USE PATTERN

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1. General Information

Id 3806-34-6

Date 18.12.2006

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2. Physico-Chemical Data

Id 3806-34-6

Date 18.12.2006

2.1 MELTING POINT

2.2 BOILING POINT

2.3 DENSITY

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

2.5 PARTITION COEFFICIENT

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

3. Environmental Fate and Pathways

Id 3806-34-6

Date 18.12.2006

3.1.1 PHOTODEGRADATION

3.1.2 STABILITY IN WATER

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

- 4.1 ACUTE/PROLONGED TOXICITY TO FISH
- 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES
- 4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE
- 4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA
- 4.5.1 CHRONIC TOXICITY TO FISH
- 4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES
- 4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS
- 4.6.2 TOXICITY TO TERRESTRIAL PLANTS
- 4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS
- 4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES
- 4.7 BIOLOGICAL EFFECTS MONITORING
- 4.8 BIOTRANSFORMATION AND KINETICS
- 4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

| | |
|----------------------|---|
| Type | : Sub-acute |
| Species | : rat |
| Sex | : no data |
| Strain | : Wistar |
| Route of admin. | : gavage |
| Exposure period | : 7 days |
| Frequency of treatm. | : daily |
| Post exposure period | : no |
| Doses | : 100, 400 and 1000 mg/kg bw/d |
| Control group | : no data specified |
| NOAEL | : 1000 mg/kg bw |
| Method | : other: range finding study for OECD 421 |
| Year | : 2006 |
| GLP | : no data |
| Test substance | : as prescribed by 1.1 - 1.4 |

Result : There were no clinical signs, no deaths, no differences in body weights or food intake, no treatment related organ weight changes or gross pathological changes.

Test substance : ca. 95%

Reliability : (2) valid with restrictions
Guideline study, but no data on GLP

18.12.2006

(1)

5.5 GENETIC TOXICITY 'IN VITRO'

5.6 GENETIC TOXICITY 'IN VIVO'

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

| | |
|---------------------------|--|
| Type | : One generation study |
| Species | : rat |
| Sex | : male/female |
| Strain | : other: Hsd-Cpb |
| Route of admin. | : gavage |
| Exposure period | : males: 2 weeks prior to mating, during mating and 2 weeks post-mating; females: 2 weeks prior to mating through PND 4 |
| Frequency of treatm. | : daily |
| Premating exposure period | |
| Male | : 2 weeks |
| Female | : 2 weeks |
| Duration of test | : see exposure period |
| No. of generation studies | : 1 |
| Doses | : 100, 400 and 1000 mg/kg bw |
| Control group | : yes, concurrent vehicle |
| NOAEL parental | : 1000 mg/kg bw |
| NOAEL F1 offspring | : 1000 mg/kg bw |
| Result | : no effects on fertility |
| Method | : OECD Guide-line 421 |
| Year | : 2006 |
| GLP | : yes |
| Test substance | : as prescribed by 1.1 - 1.4 |
| Method | : The test item was suspended in 0.5% aqueous carboxymethyl cellulose and administered by oral gavage to groups of 10 rats/sex at doses of 100, 400 and 1000 mg/kg bw/d. Animals from all groups were observed for clinical signs, behavior, physical abnormalities and changes in body weight and food consumption. The numbers, weight, survivability and mortality of pups were observed during lactation period. The animals were subjected to detailed necropsy at sacrifice. Histopathological examination was performed on the ovaries, testes, and epididymes (with special emphasis on stages of spermatogenesis and histopathological examination of interstitial testicular cell structure) of high dose group and control group. The data were statistically analyzed. |
| Result | : There were no treatment related clinical signs at any dose tested. The parturition performance in females was unaffected and there were no signs of dystocia. There were no deaths. Body weights and food intake were unaffected by treatment with the test item. Maternal body weights and food intake during different intervals of gestation and lactation periods were unaffected by treatment. There were no treatment related effects on pre-coital interval and gestation length in the treated groups when compared to controls. The mean number and weight of male and female pups and for the combined sex were unaffected by the treatment at all doses. The number of live litters, sex ratio at birth, number of pups dead at birth, number of pups dead/cannibalized on day 1, up to day 4, the number of pups alive on days |

5. Toxicity

Id 3806-34-6

Date 18.12.2006

0, 1, and 4, live birth index, 24 hour survival index and day 4 survival index were unaffected by the treatment at all doses tested when compared to controls. The fertility indices were unaffected by the treatment at all doses tested. There were no treatment related changes in terminal body weights, organ weights and organ weight ratios in the males. There were no treatment related gross or histopathological changes in the males and females.

Test substance : ca. 95%

Reliability : (1) valid without restriction
Guideline study

Flag : Critical study for SIDS endpoint

18.12.2006 (1)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species : rat

Sex : male/female

Strain : other: Hsd-Cpb

Route of admin. : gavage

Exposure period : males: 2 weeks prior to mating, during mating and 2 weeks post-mating;
females: 2 weeks prior to mating through PND 4

Frequency of treatm. : daily

Duration of test : see exposure period

Doses : 100, 400 and 1000 mg/kg bw/d

Control group : yes, concurrent vehicle

NOAEL maternal tox. : 1000 mg/kg bw

NOAEL teratogen. : 1000 - mg/kg bw

Result : no effects on developmental toxicity or teratogenicity

Method : other: OECD 421

Year : 2006

GLP : yes

Test substance : as prescribed by 1.1 - 1.4

Method : The test item was suspended in 0.5% aqueous carboxymethyl cellulose and administered by oral gavage to groups of 10 rats/sex at doses of 100, 400 and 1000 mg/kg bw/d. Animals from all groups were observed for clinical signs, behavior, physical abnormalities and changes in body weight and food consumption. The numbers, weight, survivability and mortality of pups were observed during lactation period. The animals were subjected to detailed necropsy at sacrifice. Histopathological examination was performed on the ovaries, testes, and epididymes (with special emphasis on stages of spermatogenesis and histopathological examination of interstitial testicular cell structure) of high dose group and control group. The data were statistically analyzed.

Result : There were no treatment related clinical signs at any dose tested. The parturition performance in females was unaffected and there were no signs of dystocia. There were no deaths. Body weights and food intake were unaffected by treatment with the test item. Maternal body weights and food intake during different intervals of gestation and lactation periods were unaffected by treatment. There were no treatment related effects on pre-coital interval and gestation length in the treated groups when compared to controls. The mean number and weight of male and female pups and for the combined sex were unaffected by the treatment at all doses. The number of live litters, sex ratio at birth, number of pups dead at birth, number of pups dead/cannibalized on day 1, up to day 4, the number of pups alive on days

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0, 1, and 4, live birth index, 24 hour survival index and day 4 survival index were unaffected by the treatment at all doses tested when compared to controls. The fertility indices were unaffected by the treatment at all doses tested. There were no treatment related changes in terminal body weights, organ weights and organ weight ratios in the males. There were no treatment related gross or histopathological changes in the males and females.

Test substance : ca. 95%
Reliability : (1) valid without restriction
Guideline study
Flag : Critical study for SIDS endpoint
18.12.2006

(1)

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7. Eff. Against Target Org. and Intended Uses

Id 3806-34-6
Date 18.12.2006

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

9. References

Id 3806-34-6

Date 18.12.2006

- (1) Advinus Therapeutics Private Limited (2006)
Reproduction/Developmental Toxicity Screening Test by Gavage
with 2,4,8,10-Tetraoxa-3,9-Diphosphaspiro[5.5]Undecane,
3,9-Bis (Octadecyoxo)-(9CL) in Wistar Rats.

10. Summary and Evaluation

Id 3806-34-6

Date 18.12.2006

10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT